UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S OPPOSITION TO THE UNITED STATES' OBJECTIONS TO AUGUST 13, 2007 ORDER BY MAGISTRATE JUDGE BOWLER

Pursuant to Fed. R. Civ. P. Rule 72(a) and Rule 2(b) of the Rules for the United States Magistrates in the United States District Court for the District of Massachusetts, Defendant Abbott Laboratories, Inc. files this response to the United States' Objections to August 13, 2007 Order by Magistrate Bowler ("Gov't Objs.") (Dkt. No. 4697).

PRELIMINARY STATEMENT

The Government objects to producing 44 documents that fall within two aspects of Magistrate Bowler's ruling on Abbott's motion to compel evidence withheld under the deliberative process privilege. First, the Government objects to producing 41 documents that "expressly reference Abbott Laboratories, Inc. ("Abbott") and/or the subject drugs." August 13 Order; Gov't Objs. at 4-5. Although these documents are responsive to Abbott's discovery requests and expressly refer to Abbott and/or the Subject Drugs, the Government contends that "many" of these documents are "completely tangential." Gov't Objs. at 5. Second, under an inappropriately narrow interpretation of Magistrate Bowler's ruling, the Government objects to producing three documents that "concern the government's knowledge of the common use of spreads with respect to published AWPs." August 13 Order; Gov't Objs. at 5. The Government contends that these documents are "similarly tangential."

Both of the Government's Objections suffer from the same deficiency: Apart from addressing only a *single* document from each category—no doubt the document that best represents its position—the Government provides no legitimate reason to overturn Magistrate Bowler's ruling. In any event, the Government has once again failed to articulate any particular harm the Government would suffer if these particular 44 documents—and others, under a reasonable interpretation of the August 13 Order—were disclosed under a protective order.

ARGUMENT

I. THE GOVERNMENT'S OBJECTIONS FAIRLY PLACE ONLY TWO DOCUMENTS AT ISSUE.

As discussed in Abbott's Objections to Magistrate Judge Bowler's August 13, 2007 Order ("Abbott Objs.") (Dkt. No. 4698), Magistrate Bowler did not review any of the documents the Government has withheld under the deliberative process privilege before issuing her ruling. Instead, that part of Magistrate Bowler's ruling requiring production of "the approximately 60 documents that expressly reference Abbott Laboratories, Inc. ("Abbott") and/or the subject drugs" seems to have resulted from the Government's statement that only approximately 60 of the 699 withheld documents "mentioned Abbott in any way." July 20, 2007 Hrg. Tr. at 14. The Government made reference to the number of documents referring to Abbott as "one sort of compromise step that I think we could take here that might facilitate this." *Id.* Judge Bowler seemed amenable to such a compromise. *See id.* ("You know, the two least favorite words for Judges are *in camera* and *pro se*.").

After using the "Abbott-reference-only" concept to avoid production of otherwise responsive documents, the Government now changes its mind. It now argues the "fact that a document references Abbott or a subject drug is not a reliable indicator that the document is sufficiently relevant to the case . . . ." Gov't Objs. at 8-9.

It may well be that one or perhaps more of the withheld documents that expressly reference Abbott and/or the Subject Drugs are of little relevance to this case. For example, the document attached as Exhibit 2 to the Government's motion (HHC903-0520-0523), purportedly relating to "coverage of infusion pumps," does appear to be of little interest. But the Government's ability to find one such seemingly irrelevant document, and provide that one document to the Court under seal, provides no basis for this Court to overturn this aspect of Magistrate Bowler's August 13 Order.

It is unclear what exactly the Government would have the Court do with the 41 responsive documents that expressly reference Abbott and/or the Subject Drugs. Surely the Government does not expect the Court to overturn this part of Magistrate Bowler's ruling on the basis of an *in camera* review of one document. If the Government wanted the Court to overturn this aspect of Magistrate Bowler's ruling, it was obligated to turn over all 41 documents so that the Court could conduct a reasonable review of the material. The Government's statement that it would be "willing to proffer these 44 documents for an *in camera* review" is insufficient. Gov't Objs. at 5; *Athridge v. Aetna Casualty & Surety Co.*, 184 F.R.D. 181, 190-91 (D.D.C. 1998) (noting relevance objection is "really no objection at all as it does not address why potentially responsive documents are being withheld" and would allow the producing party to "arrogate[ ] to itself the authority to decide the question of relevance which is unquestionably the decision of the judge."). In short, apart from the Government's say-so, there is simply no basis to disturb Magistrate Bowler's quite reasonable presumption that documents that were both responsive to Abbott's document requests *and* mention Abbott and/or the Subject Drugs should be discoverable.[1]

[1] Abbott's document requests are not nearly as broad as the Government claims. *See* Gov't Objs. at 8 ("The Magistrate Judge's Order, when coupled with the enormous breadth of Abbott's document requests, necessarily leads to situations such as this one, where privileged documetns have to be disclosed because of stray

But just as there might be some documents that expressly reference Abbott and/or the Subject Drugs that are irrelevant, there are undoubtedly documents that do *not* expressly reference Abbott and/or the Subject Drugs that *are* very relevant to this litigation. *See* Abbott Objs. at 18. Should the Court accept the Government's request to conduct an *in camera* review of the 44 documents the Government has withheld under the deliberative process privilege, it should also review potentially relevant documents beyond those proffered documents.[2] After all, Magistrate Bowler's order effectively split the difference between Abbott's position and the Government's; it is only fair that if one side of that balance is altered to remove documents the Government now contends are irrelevant, Abbott should have an equal opportunity to include other documents that appear to be particularly relevant. To assist in such an *in camera* review, Abbott has identified on the attached Exhibit A a sample of 50 documents that, in addition to those documents that expressly reference Abbott and/or the Subject Drugs, appear, based on the privilege log descriptions, to be particularly relevant. Abbott respectfully requests that any *in camera* review include at least these documents as well.[3]

In addition to the 41 documents that expressly reference Abbott and/or the Subject Drugs, the Government states that there are three documents that "concern the government's knowledge of the common use of spreads with respect to published AWPs." August 13 Order; Gov't Objs.

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references to Abbott or a subject drug, notwithstanding the fact that that they have no pertinence to the relevant issues in this case."). Abbott has made clear to the Government that it is not seeking documents that relate solely to "coverage" issues, and have no bearing on the Government's polices on reimbursing providers for the administering or dispensing of drugs.

[2] For the reasons set forth in Abbott's Objections and prior briefing, Abbott does not believe there is any need for an *in camera* review of the documents withheld by the Government solely under the deliberative process privilege. That privilege has no place in this case given the Government's allegations against Abbott.

[3] In addition, Abbott respectfully refers the Court to the deposition testimony summarized on pages 8-10 of Abbott's reply brief in support of its motion to compel, Docket No. 4474; the deposition transcripts are attached as exhibits to that motion. Abbott believes a ruling on this testimony will provide important guidance to the parties on the appropriateness of deliberative process privilege instructions in the future depositions.

at 5. The Government has provided only one of the three documents to the Court for an *in camera* review, HHC906-0001-0002 (filed under seal as Exhibit 3 to the Government's Objections). The Government states the document is dated January 23, 2002 and relates to Lupron marketing conduct. The Government argues it is irrelevant because it is "outside the time frame of the United States' First Amended Complaint" and "contains no reference to any of the drugs at issue in the case." Gov't Objs. at 10. The Government, as has so often been the case throughout this litigation, is trying to have it both ways. The Government has successfully argued that it should get Abbott documents through 2003, even though that is beyond the time-frame of its complaint. Moreover, the Government has argued that Abbott should be compelled to produce any document, regardless of drug and regardless of Abbott division, relating to how Abbott "priced and marketed drugs so as to develop pattern and practice evidence." United States' Objections to July 19, 2007 Order by Magistrate Judge Bowler at 3, 12 (Dkt. No. 4627). The Government has specifically argued that it should receive documents from TAP, the manufacturer of Lupron, arguing such documents "are highly relevant to the Government's case." *Id.* at 16-18. If, as the Government asserts, documents relating to TAP marketing the spread are discoverable in this case, it should be a two-way street and HHC906-0001-0002 should be produced.

II. THE BALANCING TEST—INCLUDING FOR ANY DOCUMENTS THAT CONCERN THE GOVERNMENT'S KNOWLEDGE OF SPREADS—TIPS STRONGLY IN FAVOR OF DISCLOSURE.

For the reasons set forth in Abbott's Objections, Abbott believes Magistrate Bowler's ruling should be interpreted to require the Government to produce, at a minimum, all evidence concerning the Government's knowledge of differences between published AWPs and provider acquisition costs—the spread. Just as documents that reflect any effort by Abbott to market the spread or manipulate the published AWP lie at the heart of Plaintiffs' case, documents that relate

to the Government's knowledge of spreads lie at the heart of Abbott's defense. This is a fraud case. Evidence of what the Government knew and did not know about published AWPs is relevant to whether it justifiably relied upon reported prices. A "person claiming justifiable reliance is required to use his senses, and cannot recover if he blindly relies upon a misrepresentation the falsity of which would be patent to him if he utilized his opportunity to make a cursory examination or investigation." *Collins v. Huculak*, 783 N.E.2d 834, 839 (Mass. App. Ct. 2003); *see also Neptuno Treuhand-Und Verwaltungsgesellschaft Mbh v. Arbor*, 692 N.E.2d 812, 818 (Ill. App. Ct. 1998) ("In determining whether there was justifiable reliance, it is necessary to consider all of the facts within a plaintiff's actual knowledge as well as those that he could have discovered by the exercise of ordinary prudence.").

The Government admits that a "larger number of the documents on the logs reflect internal deliberations among government employees regarding drug prices generally, and many reflect some knowledge of the existence of spreads on certain drugs." Gov't Objs. at 10. Those documents should be produced. Regardless of the drug, Abbott's search for the Government's knowledge of spreads between AWP and acquisition costs is reasonably calculated to lead to the discovery of relevant evidence. If the Government knew about "mega-spreads" for one drug, but did nothing about it, that information is relevant to the issue of what the Government would have done regarding the Subject Drugs. It is also relevant to whether the Government justifiably relied upon the published AWPs for the Subject Drugs. If, for example, the Government knew that over half of the multi-source drugs tested in an OIG study had acquisition costs less than 50% of published AWPs, that knowledge is relevant to whether the Government really believed—certainly, whether it should have believed—that the published AWPs for the multi-source Subject Drugs were an indicia of market prices. *See Security Ins. Co. of Hartford v. Trustmark Ins. Co.*, 218 F.R.D. 18, 23 (D. Conn. 2003) (discovery into other transactions

unrelated to the action at hand was appropriate in fraud and negligent misrepresentation case, as "practice or custom evidence may be relevant to a determination of whether a misrepresentation was material in the particular instance"); *Marks v. Global Mortgage Group, Inc.*, 218 F.R.D. 492, 497 (S.D. W.Va. 2003) (where plaintiff raised claim of fraud, "evidence of similar transactions was relevant to the plaintiff's claims and therefore, discoverable").

Despite repeated invitations, the Government has failed to cite a single case for the absurd proposition that "government knowledge" evidence is relevant *only* to the issue of Abbott's *scienter*. Numerous cases decided under the False Claims Acts—including those cited by the Government—recognize that such evidence is potentially relevant to a number of defenses apart from the *scienter* issue. *See* Abbott Objs. at 12-14. Plaintiffs' common law fraud claim requires affirmative proof of justifiable reliance. The Government's citation to this Court's prior observations in a different case that knowledge of the spreads of other drugs *might* be irrelevant (Gov't Objs. at 12) misses the point. This is discovery, not trial. Relevancy must be "broadly construed at the discovery stage of litigation and a request for discovery should be considered relevant if there is any possibility that the information sought may be relevant to the subject matter of the action." *See Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984). The Government, "having no incentive to err on the side of disclosure," should not be permitted to "arrogate[ ] to itself the authority to decide the question of relevance which is unquestionably the decision of the judge." *Athridge*, 184 F.R.D. at 190-91. It is the Court, not the Government, that is responsible for deciding if the "larger number" of withheld documents relating to internal deliberations about drug prices and spreads (Gov't Objs. at 10) are discoverable. The failure to do so is reversible error.[4]

[4] *See Saldana-Sanchez v. Lopez-Gerena*, 256 F.3d 1, 8 (1st Cir. 2001) (finding reversible error when district "court's discovery order was plainly wrong and resulted in substantial prejudice to the aggrieved party"); *Shields v. Twiss*, 389 F.3d 142, 149 (5th Cir. 2004) ("when a party is not given a full and fair opportunity to discover

The Government's claims that Abbott can make its defenses with other evidence, and that the "United States has not blocked Abbott's discovery into what individual government employees knew, believed, understood, or agreed to in the area of drug reimbursement" (*id.* at 13) is demonstrably false. In fact, the Government has repeatedly asserted the deliberative process privilege to block its witnesses from answering very relevant questions regarding drug reimbursement during deposition. Abbott set forth a number of specific examples in its reply brief in support of its renewed motion to compel. *See* Dkt. No. 4474 at 8-10. For example, the Government has allowed no testimony about communications between OIG and CMS at "entrance" an "exit" conferences for any of the key OIG reports. *See, e.g.,* Ex. B at 297-98 (OIG Deputy Regional Inspector General Linda Ragone).

The Government has continued to block highly relevant deposition testimony since Abbott's prior briefing. Just last Friday, the Government liberally asserted the privilege to block Robert Niemann—widely recognized as HCFA's most knowledgeable employee on Medicare drug reimbursement issues—from answering questions on a number of important topics. Among other things, the Government would not let Mr. Niemann testify about (1) whether there were individuals within HCFA who preferred to use published AWPs despite knowing of the large difference between published AWPs and acquisition costs, (2) whether he had had discussions with HCFA about the implications of abandoning the AWP-based methodology on access to care, and (3) his knowledge of discussions about the impact that politics had on maintaining the use of AWP methodology. *See* Ex. C at 170-88 (rough transcript).

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information essential to its opposition to summary judgment, the limitation on discovery is reversible error"); *Travelers Ins. Co. v. Transport Ins. Co.*, 846 F.2d 1048, 1053 (7th Cir. 1988) ("While a district court is vested with broad discretion in denying discovery, it is reversible error if the denial resulted in actual and substantial prejudice to the complaining litigant.").

The Government's focus on the number of documents it has produced relating to the Government's knowledge and decision-making in the area of drug reimbursement is utterly beside the point. The Government cites no case law—and there is none—that supports the proposition that a party may withhold, at its own choosing, relevant documents simply because it has produced a significant majority of the other responsive documents in its possession. Abbott suspects that the Government would not be satisfied by such a selective production from Abbott.

Moreover, there is reason to believe that some of the withheld documents may be the cream of the crop. For example, the minutes of the "entrance" and "exit" conferences between OIG and HCFA relating to key OIG reports are particularly relevant. These documents offer an unbiased and contemporaneous insight into the reasons why CMS continued to allow use of published prices despite knowledge of their unreliability. These minutes may also assist in reminding Government witnesses of facts and decision-making that time has caused them to forget. *See, e.g.*, Ex. B at 285-303 (Ragone); Ex. D at 611-12 (OIG Regional Inspector General Robert Vito). Not surprisingly, these witnesses have testified that a review of the meeting minutes might very well help them remember key facts as they occurred. *See, e.g.*, Ex. B at 296-97 (Ragone).

The Government does not dispute that the third and fourth prongs of the balancing test—the Government's role in the case and the seriousness of the litigation—strongly favor disclosure here. *See* Gov't Objs. at 15-16. Instead of making any sort of argument regarding these factors, the Government merely reiterates its flawed relevance argument. As one of the cases cited by the Government makes clear, the Government's role as a party to the litigation skews the balancing test strongly in favor of disclosure. *See United States v. Hooker Chems. & Plastics Corp.*, 123 F.R.D. 3, 12 (W.D.N.Y. 1988) ("Perhaps most importantly, the government asserting the privilege in this case is a party to the litigation.").

The Government provides nothing of substance to overcome the presumption that its role as plaintiff in the litigation makes it very difficult for it to withhold documents under the deliberative process privilege. The Government fails to articulate any real harm that would result from disclosure of the documents under a protective order. For the reasons set forth in Abbott's Objections (at 21-25), this Court should give little to no credence to the after-the-fact, lawyer-driven, conclusory statements made in the declarations of Ms. Norwalk and Mr. Vito. There is nothing in those declaration that even attempts to provide "precise and certain reasons for preserving the confidentiality of the requested information." *Mobil Oil Corp. v. Dep't of Energy*, 102 F.R.D. 1, 6 (N.D.N.Y. 1983). All the Government has done is to "merely . . . paraphrase . . . the rational for the deliberative- process privilege described in the case law," which is plainly insufficient. *Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 604 (S.D.N.Y. 1991).

Finally, if the Government persists in refusing to allow witnesses to answer important, relevant questions—and if Abbott is unsuccessful in its efforts to overrule those instructions—the Government's assertion of the privilege and instructions to witnesses should be played to the jury. The Government's assertion of the privilege comes at a cost. The jury should know what questions the Government will not allowed to be answered. For example, the jury should be entitled to observe the following exchange:

> Q. I know you're going to be instructed not to answer, but I do have to put the questions on the record, Ms. Ragone. So let me get this straight. You sit down in a room, at a conference table like this with folks from HCFA; you tell them that AWP exceeds acquisition costs, as defined in the report, by up to ten times, right?
>
> A. Yes.
>
> Q. You tell them that the OIG recommends that they stop paying that high an amount for prescription drugs, right?

MR. DRAYCOTT [Government counsel]: Objection to the extent that you're asking for the contents of her communications to HCFA during the exit conference.

MR. COOK [Abbott counsel]: If you'd just instruct her not to answer. Are you instructing her not to answer?

MR. DRAYCOTT: I am.

BY MR. COOK: So you make whatever communications you do to HCFA in these exit conferences—

MR. DRAYCOTT: Objection.

BY MR. COOK: —after giving them a copy of this report, right?

MR. DRAYCOTT: Objection. And you're instructed not to answer.

BY MR. COOK: And you make your recommendations, correct?

MR. DRAYCOTT: You can answer that question.

THE WITNESS: During the exit conferences, we will tell them the findings and recommendations.

BY MR. COOK: And you encourage them, that is, officials at HCFA, to reimburse prescription drugs based upon something other than the published average wholesale price?

MR. DRAYCOTT: Objection. You're instructed not to answer.

BY MR. COOK: And, in fact, you do so heatedly, correct?

MR. DRAYCOTT: Objection. And you're instructed not to answer.

BY MR. COOK: And they respond?

MR. DRAYCOTT: You can answer whether or not they responded.

THE WITNESS: If they have comments, they will respond when we provide the findings and recommendations.

BY MR. COOK: Did they explain why HCFA continued to pay based upon AWP, notwithstanding the fact that HCFA knew average wholesale price could exceed acquisition cost by as much as ten times?

> MR. DRAYCOTT: You can answer as to whether or not they responded without revealing the response, if you remember.
>
> THE WITNESS: I believe that they stated why they were using the reimbursement strategy they were using at that time.
>
> BY MR. COOK: And what was their explanation?
>
> MR. DRAYCOTT: Objection. And you're instructed not to answer.
>
> BY MR. COOK: Why do you believe HCFA continued to use average wholesale price to pay for Medicare Part B drugs after you issued this report in December 1997?
>
> MR. DRAYCOTT: Objection. And you're instructed not to answer to the extent your belief is based on communications from HCFA during an exit conference.

Ex. B at 481-83 (Ragone).

CONCLUSION

For the foregoing reasons, the Court should reject the relief requested in the United States' Objections to August 13, 2007 Order by Magistrate Judge Bowler. Furthermore, the Court should reject the Government's inappropriately narrow interpretation of Magistrate Bowler's August 13 Order and require the Government to immediately produce, at a minimum, all evidence that in any way concerns the Government's knowledge of differences between published AWPs and provider acquisition costs.

Dated: September 17, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S OPPOSITION TO UNITED STATES' OBJECTIONS TO AUGUST 13, 2007 ORDER BY MAGISTRATE JUDGE BOWLER to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 17th day of September, 2007.

/s/ David S. Torborg
David S. Torborg